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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,339	02/25/2004	Reynolds G. Gorsuch	TRANSVI.017A	4556

20995 7590 09/18/2006

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EXAMINER

CRAIG, PAULA L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,339

Applicant(s)

GORSUCH ET AL.

Examiner

Paula L. Craig

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 and 64-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-34 and 36-54 is/are rejected.
- 7) ☐ Claim(s) 35 and 55-63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/25/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/24/04 6/29/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II and Species F in the reply filed on June 26, 2006 is acknowledged. Claims 1-31 and 64-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

Specification

2. For Claim 35, the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Claim Objections

3. Claims 32-63 are objected to because of the following informalities: In Claim 32, line 8, "the said one or more" should be "one or more of said plurality of". In Claim 34, lines 1 and 2, "comprising" should be "wherein said plurality of elongated hollow tubes comprises". In Claim 34, lines 3-5, "a first hollow tube", "a second hollow tube", and "a first and a second hollow tube", should be "the first hollow tube", "the second hollow tube", and "the first and the second hollow tube". In Claims 52-54, "membrane fiber wall" lacks antecedent basis. In Claims 55-60, "lower mass density zone" and "higher mass density zone" lack antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 32-34 and 36-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,224,926 to Gorsuch in view of U.S. Patent Application Publication No. 2002/0046970 to Murase et al.

8. For Claim 32, Gorsuch '926 teaches a filter device for being implanted in a blood vessel for carrying out in-vivo plasma separation, including a plurality of elongated hollow tubes and a plurality of elongated fibers, each fiber having a microporous fiber wall with an outer wall surface and an inner wall surface defining an interior lumen extending along the length thereof (Abstract, Figs. 1-7, and Claims 1 and 14). Each fiber has a first end and a second end secured to one or more of the elongated hollow tubes, wherein the interior lumen of each of the fibers communicates with the interior of one or more of the hollow tubes (Figs. 1-7 and Claims 1, 14, and 16). Gorsuch '926 does not teach the fibers including a continuous filament embedded in the microporous fiber wall. However, reinforcement of a filter wall with a continuous filament is well known in the art. Murase confirms this and teaches a filter wall with an embedded continuous filament to provide a high tensile/rupture strength (Abstract, Figs. 3-6, paragraphs 24-25 and 42, and Claims 1-2). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '926 to include an embedded continuous filament for reinforcement, as taught by Murase.

9. For Claim 33, Gorsuch '926 does not teach the fiber wall morphology of each of the elongated microporous fibers being asymmetrical. Murase teaches the fiber wall morphology of each elongated microporous fiber being asymmetrical between the inner wall surface and the outer wall surface, the fiber wall having a higher mass density zone

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adjacent to the outer wall surface and a lower mass density zone adjacent to the inner wall surface, the higher mass density zone having a smaller average nominal pore size than the average nominal pore size in the lower mass density zone (paragraphs 26-27 and 60, and Claim 4). Murase teaches that this arrangement is preferred because the dense layer can be made thin, and the permeation performance is improved and homogenized (paragraph 27). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '926 to include the fiber wall morphology of each elongated microporous fiber being asymmetrical between the inner wall surface and the outer wall surface, the fiber wall having a higher mass density zone adjacent to the outer wall surface and a lower mass density zone adjacent to the inner wall surface, the higher mass density zone having a smaller average nominal pore size than the average nominal pore size in the lower mass density zone, as taught by Murase, so that the dense layer can be made thin and the permeation performance improved and homogenized, as taught by Murase.

10. For Claim 34, Gorsuch '926 teaches first and second elongated hollow tubes extending substantially parallel along the length thereof, a first end of each of the elongated microporous fibers secured to the first hollow tube and the second end of each of the fibers is secured to the second hollow tube with the interior fiber lumen of each fiber communicating with the interior of the first and the second hollow tube (Claims 14 and 27).

11. For Claim 36, Gorsuch '926 does not teach filaments. Murase teaches a filament extending along the fiber wall substantially uniformly between the inner wall surface and

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the outer wall surface (Figs. 3, 4, 5, and 6). Murase teaches that burying the filament within the hollow tube is preferable for improving the mechanical physical property (paragraph 42). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '926 to include the filament extending along the fiber wall substantially uniformly between the inner wall surface and the outer wall surface, as taught by Murase, to improve the mechanical physical property, as taught by Murase.

12. For Claim 37, Gorsuch '926 does not teach filaments. Murase teaches a filament extending along the fiber wall substantially equidistant between the inner wall surface and the outer wall surface (Figs. 3, 4, 5, and 6). Murase teaches that burying the filament within the hollow tube is preferable for improving the mechanical physical property (paragraph 42). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '926 to include the filament extending along the fiber wall substantially equidistant between the inner wall surface and the outer wall surface, as taught by Murase, to improve the mechanical physical property, as taught by Murase.

13. For Claim 38, Gorsuch '926 does not teach the filament having a substantially uniform tensile strength along its length. However, it is well known in the art for a reinforcing filament to have a substantially uniform tensile strength along its length. It would have been obvious to one of ordinary skill in the art at the time of the invention for the filament to have a substantially uniform tensile strength along its length.

14. For Claims 39-43, Gorsuch '926 does not teach the filament occupying less than about 15%, about 10%, or about 0.01% or about 0.2% to about 2% of the fiber wall cross-sectional area of the fiber. Murase teaches the filament occupying less than 10%

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or about 0.02% to about 2% of the fiber wall cross-sectional area of the fiber (paragraphs 58, 90, 94, 96, 98, and 100). The percentage of the fiber wall cross-sectional area of the fiber occupied by the filament is a result effective variable, since it affects permeability. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980). Murase teaches that the amount of the fiber wall cross-sectional area occupied by the filament is preferably 10% or less to retain the permeation performance of the filter and avoid resistance to the passage of liquid (paragraphs 58-60). Murase teaches an example of a filament occupying 2% of the cross-sectional area (paragraph 100). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '926 to have the filament occupy less than about 15% or about 10%, or between about 0.01% or 0.2% and about 2% of the fiber wall cross-sectional area of the fiber, as taught by Murase, to retain the permeation performance of the filter and avoid resistance to the passage of liquid, as taught by Murase.

15. For Claim 44, Gorsuch '926 does not teach the filament having a tensile strength. The tensile strength of the filament is a result effective variable, since it affects the strength of the reinforced fiber. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. Murase teaches the filament having a tensile strength of at least about 5,000 psi, so that the filament can have a tensile strength significantly higher than the surrounding part of the fiber (paragraphs 56-57). It would have been obvious to one of ordinary skill in the art to modify Gorsuch

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'926 to include the filament having a tensile strength of at least about 5,000 psi, as taught by Murase.

16. For Claim 45, Gorsuch '926 does not teach a filament. Murase teaches the filament being made of a variety of materials (paragraph 46). Murase teaches the filament including fiberglass, polypropylene, or polyamide (paragraphs 46-52). It would have been obvious to one of ordinary skill in the art to manufacture the filament from a suitable material, as taught by Murase.

17. For Claim 46, Gorsuch '926 does not teach a filament. Murase teaches the fiber having two filaments (paragraphs 93 and 97). Murase teaches that the number of filaments can be changed in accordance with the physical properties required (paragraph 85). It would have been obvious to one of ordinary skill in the art to have an appropriate number of filaments, as taught by Murase, to provide the physical properties required, as taught by Murase.

18. For Claim 47, Gorsuch '926 does not teach a filament. Murase teaches the filament including fiberglass, polypropylene, or polyamide (paragraphs 46-52).

19. For Claims 48 and 49, Gorsuch '926 does not teach a filament. Murase teaches each of the filaments having a cross-sectional area occupying between about 0.2% and about 2% or about 0.5% and about 5% of the cross-sectional area of the fiber, as described above for Claims 39-43 in paragraph 14. It would have been obvious to one of ordinary skill in the art to modify Gorsuch to include each of the filaments having a cross-sectional area occupying between about 0.2% and about 2% of the cross-

sectional area of the fiber, for the same reasons as described for Claims 39-43 in paragraph 13.

20. For Claim 50, Gorsuch '926 does not teach the fiber wall structure including a continuous change in mass density from the outer wall surface to the inner wall surface. Murase teaches the fiber wall structure including a continuous change in mass density from the outer wall surface to the inner wall surface (paragraphs 26-27 and 60). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '926 to include the fiber wall structure including a continuous change in mass density from the outer wall surface to the inner wall surface, for the same reasons as described above for Claim 33 in paragraph 9.

21. For Claim 51, Gorsuch '926 does not teach the fiber wall structure comprising a continuum of voids bounded by solid frames. Murase teaches the fiber wall structure including a continuum of voids bounded by solid frames (paragraph 27). Murase teaches that this arrangement improves permeation performance (paragraph 27). It would have been obvious to modify Gorsuch '926 to have the fiber wall structure include a continuum of voids bounded by solid frames, as taught by Murase, to improve permeation performance, as taught by Murase.

22. For Claims 52-54, Gorsuch '926 does not teach the fiber wall having two, three, or four mass density zones. Murase teaches the fiber wall having two, three or four mass density zones and each of the zones being characterized by a different average nominal pore size (note Murase teaches a continuous change in mass density, paragraph 26-27 and 60). Murase teaches that this improves permeation performance

(paragraph 27). It would have been obvious to modify Gorsuch '926 to include the fiber wall having two, three, or four mass density zones, as taught by Murase, to improve permeation performance, as taught by Murase.

23. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,561,996 to Gorsuch in view of U.S. Patent Application Publication No. 2002/0046970 to Murase et al.

24. For Claim 32, Gorsuch '996 teaches a filter device for being implanted in a blood vessel for carrying out in-vivo plasma separation, including a plurality of elongated hollow tubes and a plurality of elongated fibers, each fiber having a microporous fiber wall with an outer wall surface and an inner wall surface defining an interior lumen extending along the length thereof (Fig. 6, col. 7, lines 10-27, and col. 8, lines 10-11). Each fiber has a first end and a second end secured to one or more of the elongated hollow tubes, wherein the interior lumen of each of the fibers communicates with the interior of one or more of the hollow tubes (Fig. 6, col. 7, lines 10-27, and col. 8, lines 10-11). Gorsuch '996 does not teach the fibers including a continuous filament embedded in the microporous fiber wall. However, reinforcement of a filter wall with a continuous filament is well known in the art. Murase confirms this and teaches a filter wall with an embedded continuous filament to provide a high tensile/rupture strength (Abstract and Figs. 3-6). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '996 to include an embedded continuous filament for reinforcement.

Double Patenting

25. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claim 32 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 10 of U.S. Patent No. 6,899,692 to Gorsuch et al. in view of U.S. Patent Application Publication No. 2002/0046970 to Murase et al. Claim 10 of Gorsuch '692 has a filter device for being implanted in a blood vessel for carrying out in-vivo plasma separation, including a plurality of elongated hollow tubes and a plurality of elongated fibers, each fiber having a microporous fiber wall with an outer wall surface and an inner wall surface defining an interior lumen extending along the length thereof, each fiber having a first end and a second end secured to one or more of the elongated hollow tubes, but does not teach filaments embedded in the fiber wall. However, reinforcement of a filter wall with a continuous filament is well known in

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the art. Murase confirms this and teaches a filter wall with an embedded continuous filament (Abstract, Figs. 3-6, and Claims 1-2). It would have been obvious to one of ordinary skill in the art to modify Claim 10 of Gorsuch '692 to include an embedded continuous filament for reinforcement.

Allowable Subject Matter

27. Claims 35 and 55-63 are objected to as being dependent upon a rejected base claim, but would be allowable over the prior art if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art is U.S. Patent No. 5,224,926 to Gorsuch et al., U.S. Patent Application Publication No. 2002/0046970 to Murase et al., and U.S. Patent No. 4,882,223 to Aptel et al. There is insufficient motivation to combine the features of the various references.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571) 272-5964. The examiner can normally be reached on 6:30AM-3:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
Art Unit 3761

PLC

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

